REMARKS

Consideration of the amendments presented herein and reconsideration of all grounds for objection and rejection are respectfully requested. Claims 1-34 are pending in the application. In Applicant's Election mailed August 28, 2003, Applicant provided instructions to cancel claims 29 and 30. Upon entry of such cancellation, as shown in amendments above, claims 1-28 and 31-34 are pending in this case.

Claim Rejections - Double Patenting

The Examiner has rejected claims 1-28 and 31-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,943.

To overcome this rejection for the presently pending claims, Applicant agrees to provide, upon notification of allowance of claims, a terminal disclaimer in compliance with 37 CFR 1.321(c), with required supporting documents.. The "conflicting" referenced patent is commonly owned with the present application.

Claim Rejections - 35 USC 112, first paragraph

Claims 7, 9, 14, 17, 18, 24, 25, 28, 30 and 31 stand rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The Patent Office has stated in this regard that these claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Patent Office's position is that if the biological material constructs in these claims are not known and readily available to the public, the enablement requirements can be satisfied by a deposit of said biological materials.

Applicant respectfully requests reconsideration of this rejection based on the combination of the teachings in the art, the high level of skill in the art, and the fact that at least some precursor plasmids are currently available commercially from a company known as Microbix Biosystems, Inc. (www.microbix.com). Such precursor plasmids contain components needed to make the plasmids illustrated in the figures, including pDC111-118. In particular, such commercially available plasmids contain Ad ITR junctions and other Ad sequences (such as the packaging signal), and there are plasmids offered for sale that contain MCMV and HCMV promoters.

A price list from the web site of Microbix Biosystems, Inc. is provided as an attachment. The first kit listed, named Kit A, product number PD-01-60, contains the precursor plasmids pΔE1sp1A and pΔE1sp1B. These are shown as the starting plasmids in Figure 5A, and clear instructions are provided in each step shown in Figure 5A to obtain the plasmids shown there that are derived from pΔE1sp1A and pΔE1sp1B. The plasmids in Figure 5A, including pΔE1sp1A and pΔE1sp1B, are then used in standard restriction enzyme reactions to make the plasmids pDC111 to pDC114 as shown in Figure 5C. Similar reactions are shown in Figure 5E, which teaches how to obtain pDC115-pDC118. It is further noted that MicroBix Biosystems provides adenoviral sequences as well as plasmids.

Thus, reconsideration is respectfully requested. It is further noted that Applicant is willing to consider canceling these claims if this rejection is not overcome, in order to pursue to issue other claims in this application.

Claim Rejections - 35 USC 112, second paragraph

Claims 1, 3, 10, 16, 33 and 34 stand rejected under 35 USC 112, second paragraph, based on use of the terms "insufficient" and "sufficient." The Patent Office has stated that "these terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite

degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant has amended these claims herein, substituting the term "incapable" for "insufficient." On page 36, line 10, when discussing the "two plasmid" technique of adenvirus vector construction, the specification states, ". . . each plasmid alone is incapable of generating infectious virus." The term so substituted is definite and is based on examples in the disclosure, particularly in view of the ample data provided (see tables in application showing the numbers of plaques obtained). Given this, and in view of the high level of skill in the art, one or ordinary skill in the art is reasonably apprised of the scope of the invention.

One these same bases the term "sufficient" is replaced with "capable" in claim 33, and also in claim 33"sufficient" another phrase is removed as superfluous. It is noted that the term, "sufficiently identical with said recombinase recognition target site in said first nucleic acid as to be recognized by the same site-specific recombinase which recognizes said site-specific recombinase recognition target site in said first nucleic acid" is considered an adequate functional limitation, and has not been amended to remove "sufficient." The effect of such amendments, regarding "insufficient" and "sufficient" is viewed as not narrowing the scope of these claims.

Claims 13 stands rejected under 35 USC 112, second paragraph, based on use of the term "derived from" as applied to an expression cassette. Claim 13 is amended herein to remove this term. It is noted that other amendments were made to clarify claim 13. The sum effect of such amendments is viewed as not narrowing the scope of this claim.

Claims 9, 11, 18, 25, 28 and 31 stand rejected under 35 USC 112, second paragraph, based on use of the term, stated to be vague and indefinite, "which, as needed, undergo additional modification to provide a head-to-head ITR junction." These claims are amended herein to remove this phrase, as is claim 14, which also contained such phrase. Applicant notes that this

phrase is not necessary to the meaning and sufficiency of these claims, as the limitation of the plasmids in question, having a head-to-head ITR, is provided in the relevant claims upon which these claims depend. The effect of such amendments is viewed as not narrowing the scope of these claims.

Claim Rejections - 35 USC 102

Claims 1, 2, 10, 13, 16, 20, 33 and 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kaleko et al. (WO 97/25446) ("Kaleko"). The following discussion generally explains why Kaleko is not relevant to any claim in the present application. It is noted that this conclusion was reached in a related application, serial number 09/981,648, filed 10/16/2001, during a telephone interview on July 29, 2003.

As concluded in that interview, and as apparent based on review of Kaleko, Kaleko does not teach head-to-head ITRs. Substantiation of this is found in the Kaleko disclosure, which states, in a number of places, that its nucleic acid structures may have one or the other, not both ITRs present. For instance, on page 13, regarding the first polynucleotide, "In addition to the adenoviral 5' or 3' ITR, . . ." indicates both are not present (see also page 12, lines 9-12, of Kaleko). In contrast, as noted above, the present invention claims both ITRs present to form an hth ITR junction for reasons indicated above and documented in the disclosure.

As such, reconsideration and withdrawal of this ground for rejection is respectfully requested.

Claims 1, 2, 10, 12, 13, 16, 20, 33 and 34 stand rejected under 35 USC 102(b) as being anticipated by Bett et al. (1994, Proc. Natl. Acad. Sci. USA 91:8802-6). In that this Bett et al. reference teaches homologous recombination, and the present claims are directed to recombination effectuated by site-specific recombination, the Bett et al. reference does not include all limitations of the above-noted rejected claims. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

Claims 1, 2, 10, 12, 13, 16, 19, 20, 33 and 34 under 35 USC 102(b) as being anticipated by Bett et al. (1993, J. Virology 67:5911-21). In that this Bett et al. reference teaches homologous recombination, and the present claims are directed to recombination effectuated by site-specific recombination, the Bett et al. reference does not include all limitations of the above-noted rejected claims. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

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All claims having either been placed in condition for allowance or cancelled, expedited passage of this case to issuance is respectfully solicited.

If certain terms or clauses remain in the claims as amended which the Examiner finds still present a rejection under 35 USC 112, or if the Examiner believes that any valid basis of non-patentability remains after entrance of the amendments herein and consideration of the remarks herein, the courtesy of a telephone call to the Attorney for Applicant will be most appreciated, in order to provide an opportunity to reach mutually agreeable resolution, including finding acceptable claim language in view of the claim types, the specification, and the knowledge in the field.

Respectfully submitted,

1/21/04

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Price List: Adenovirus Vector Kits and 293 Cells

Adenovirus Vector Creation Kits

- All adenovirus reagents must be ordered in complete kits unless li separately.
- Plasmids are packaged at 10 micrograms per vial.

Product #	Name	Kit Contents
PD-01-60	Kit A	pΔE1sp1A, pΔE1sp1B, pFG140 and pJM17
PD-01-61	Kit B	pAB26, pAB27, pFG140 and pFG173
PD-01-62	Kit C	pΔE1sp1A, pΔE1sp1B, pXC1, pABS.4, pFG140, pBHG10, pBHG11 and pBHGE3
PD-01-64*	AdMax™ Kit D	pDC311, pDC312, pDC315, pDC316, pBHGlox_E1,3Cre, and pFG140
PD-01-65	AdMax™ Kit E	pDC511, pDC512, pDC515 and pDC516, pBHGfrtΔE1,3FLP, and pFG140
PD-01-67	AdMax™ Kit F	pDC411, pDC412, pDC415, pDC416, pBHG10, pBHGE3 and pFG140
PD-01-66	AdCre Kit G	AdCre1, AdCreM1, AdfloxLacZ1 and Adfloxluc
PD-01-68**	AdMax™ HI-IQ Kit H	pDC315(io), pDC316(io), pBHGlox ΔE1,3Cre, pFG140, 293IQ Cells
PD-01-69**	AdMax™ HI-IQ Kit J	pDC515(lo), pDC516(io), pBHGfrt ΔE1,3FLP, pFG140, 293IQ Cells
PD-01-70	Helper Dependent Adenovirus Vector Kit K	293Cre4 cells, Adeno helper virus H14, pC4HSUgfp, pC4HSU

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Indivdual Vectors

Pr duct#	Name

PD-01-01	pΔE1sp1A
PD-01-02	pΔE1sp1B
PD-01-03	pXC1
PD-01-04	PABS.4
PD-01-05	pFG140
PD-01-06	pJM17
PD-01-07	pAB26
PD-01-08	pAB27
PD-01-09	pFG173
PD-01-10	PBHG10
PD-01-11	PBHG11
PD-01-12	PBHGE3
PD-01-19	PBHG9
PD-01-13	pCA3
PD-01-14	pCA4
PD-01-15	pCA13
PD-01-16	pCA14
PD-01-17	pCA17
PD-01-18	pCA18
PD-01-20	PHCMVsp1LacZ
PD-01-21	pMH4
PD-01-22	pMH5
PD-01-41	pMH5(I)
PD-01-29	pDC411
PD-01-30	pDC412
PD-01-31	pDC415
PD-01-32	pDC416
PD-01-42	AdCre1
PD-01-43	AdCreM1
PD-01-44	AdfloxLacZ1
PD-01-45	Adfloxluc

Permissive Cell Lines

Product#	**Name**
PD-02-01	293 Low Passage Cells
PD-02-02	293 N3S Suspension Cells
PD-02-03	293 E4pIX Cells
PD-02-05	NautCell™

Print the product list

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